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EXAMINER

LEA, CHRISTOPHER RAYMOND

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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/535,453	Applicant(s) RAND, PAUL KENNETH	
	Examiner Christopher R. Lea	Art Unit 4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 and 44-76 is/are pending in the application.
- 4a) Of the above claim(s) 1-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-41 and 44-76 is/are rejected.
- 7) ☒ Claim(s) 36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/19/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a 371 (national stage application) of PCT/EP03/13074.

Claims 1-41 & 44-76 are pending. Claims 36-41 & 44-76 are under examination.

Election/Restrictions

1. Applicant's election of Group II, claims 36-41, in the reply filed on July 24, 2008, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Newly presented claims 44-76 are determined to read on the elected invention and, as such, they will be examined with claims 36-41.

2. Claims 1-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 24, 2008.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

4. The information disclosure statement(s) (IDS) submitted on May 19, 2005, was filed before the mailing date of the first office action on the merits. The submission is in

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compliance with the provisions of 37 CFR 1.97 & 1.98. Accordingly, the information disclosure statement is being considered by the examiner.

Examiner notes that the IDS cites GB2323942 (reference 19), and, while this reference has some relevance to the instant case, Examiner believes, based on the background section of the specification, that this was intended to be reference GB2323042.

Claim Objections

5. Claim 36 is objected to because of the following informalities: The phrase "having a body" in line 1 is describing the closest noun, "powder," when clearly applicant intended it to describe the capsule. Examiner suggests deleting "for a powder" from line 1 of the claim or adding ", the capsule" after "powder" in line 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 73 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 73 is incomprehensible and unexamined as currently written as it contains such long recitations that the metes and bounds of the claimed subject matter cannot be determined.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 36-41 & 74-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Theobald et al. (UK patent application document GB2323042).

Applicant claims

Applicant claims a method for filling an inhaler/capsule with a powder.

**Determination of the scope and content of the prior art
(MPEP 2141.01)**

Theobald et al. teach, as a whole, a powder medicament nebulizer.

Claim 36: Theobald et al. teach a dry powder nebulizer (capsule) with an internal powder chamber and an inlet and outlet port (a first and second opening) and a piston

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that allows fluid communication between the inlet and outlet ports (p. 1, line 17 through p. 2, line 2). Theobald et al. also teach a method of nebulizing a powder whereby the piston is reciprocated (from sealed state to filling state) to create an air flow and push powder out of the internal chamber past the outlet port into the external environment (claim 20). Reversing these steps meets the limitations of the claim.

Claim 37: Theobald et al. teach that the result of the method of nebulizing a powder is a cloud of powder (p. 9, lines 2-3), and again when the method steps are reversed, the powder cloud is the powder source.

Claim 38: Theobald et al. teach the reciprocation of the piston (claim 20) and the skilled artisan would realize that a reciprocating piston creates a vacuum.

Claim 39: Theobald et al. teach the powder in the nebulizer is a drug (p. 9, lines 2-3).

Claim 40: Theobald et al. teach a multi-nebulizer arrangement such that all the individual nebulizers (capsules) can be opened simultaneously (p. 10, line 12-20). This also means that if the method steps are done in reverse, the capsules could all be filled simultaneously.

Claim 41: If all capsules are the same size and filled to capacity they will necessarily contain the same or substantially the same quantity of powder.

Claim 74: Theobald et al. teach the powder in the nebulizer is a drug (p. 9, lines 2-3).

Claim 75: The size of the capsule would be the determining factor in whether or not the capsule contained a unit dose. The size of the capsule is result-effect variable that can be optimized through routine experimentation.

Claim 76: Theobald et al. teach only one internal powder chamber in nebulizer (p. 1, line 17 through p. 2, line 2).

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

The difference between Theobald et al. and the instant claims is that Theobald et al. do not expressly teach the method of filling the capsule with the steps as claimed.

**Finding of *prima facie* obviousness
Rationale and Motivation (MPEP 2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to fill the nebulizers (capsules) by reversing the process of nebulizing a powder and fill the capsules with a consistent amount of powder and produce the instant invention to obtain uniform capsule filling. The skilled artisan would have been motivated to fill the capsules in this manner because uniformity of dosage amount in different capsules can be guaranteed by following this method. Further the teachings of Theobald et al. create a reasonable expectation of success for the reasons stated above.

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11. Claims 44-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Theobald et al. (UK patent application document GB2323042) as applied to claim 36 above, and further in view of Dorment (US Patent 1,410,556).

Applicant claims

Applicant claims a method for filling an inhaler/capsule with a powder.

Determination of the scope and content of the prior art (MPEP 2141.01)

Theobald et al. teach, as a whole, a powder medicament nebulizer.

The teachings of Theobald et al. as they relate to base claim 36 appear above.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the instant claims and Theobald et al. is that Theobald et al. do not expressly teach all the claimed structural elements, such as the first and second parts of the body, cap, plug sections, and channels in the plug section. This deficiency in Theobald et al. is cured by the teachings of Dorment.

Dorment teaches, as a whole, an inhaler capsule for administering medicaments.

Claim 44: Dorment teach the expanded filling (figure 2) and contracted sealing states (figure 1).

Claim 45: Dorment teach that the first opening (element 2 in figure 2) is partially obstructed and would become occluded by powder in the steps of the method.

Claim 46: Dormont teach that the bore (element 1) is stationary while the member (element 8) moves.

Claim 47: Dormont teach the body assembled in both states (figures 1 & 2).

Claim 48: Dormont teach that the bore (element 1) is stationary while the member (element 8) moves.

Claim 49: Dormont teaches that the parts in contact with each other in both states (figures 1 & 2).

Claim 50: Dormont teaches both openings closed in the sealing state (figure 1) and both openings open in the filling state (figure 2).

Claim 51: Dormont teaches that the first opening (element 2 in figure 2) is partially obstructed by the member (element 8) and that the opening would become occluded by powder in the steps of the method.

Claim 52: Dormont teaches that the first opening (element 2 in figure 2) is partially plugged by the member (element 8).

Claim 53: Dormont teaches a plug section (element 8a) spaced away from the inner surface of the first opening.

Claim 54 & 55: Dormont does teach the member having first and second outer surface portions (elements 8a and 8b). However Dormont does not teach the different outer portions being in contact with the body while in the filling state nor does Dormont teach the claimed channels on the outside of the of the plug (member). The skilled artisan would be motivated to modify the member to include these limitations because it would reduce the powder spillage and allow for finer powders to be used.

Claim 56: Dorment teaches the member having first and second outer surface portions (elements 8a and 8b) which seal the first opening (element 2) when in the sealing state (figure 1).

Claim 57: Dorment teaches moving the member (element 8) to seal the capsule and that the plug is disposed on the first part (figures 1 and 2).

Claim 58: Dorment teaches that the first and second plug sections are contiguously arranged (elements 8a and 8b in figure 2).

Claim 59: Dorment teaches the member sealingly closing the second opening (element 7) in the sealing state (figure 1).

Claim 60: Dorment teaches the first opening (element 2) in the second part (element 1).

Claim 61: Dorment teaches the second opening (element 7) in the second part (element 1)

Claim 62: Dorment teaches the second part (element 1) with an internal passageway (the space between elements 5 & 8) that connects the two openings (elements 2 & 7).

Claim 63 & 64: Dorment teaches the opening (element 2) is formed by the passageway being restricted by a shoulder (see figure 2).

Claim 65: Dorment teaches the second opening (element 7) is formed by the passageway's ending (at element 6).

Claim 66: Dorment teaches the first and second parts (elements 8 & 1, respectively) slide past each other.

Claim 67: Dorment teaches the second part (element 1) with an internal passageway (the space between elements 5 & 8) and the internal chamber is the section of the internal passageway not occupied by the member (element 8).

Claim 68: Dorment teaches that the internal chamber is the section of the internal passageway not occupied by the member (element 8).

Claim 69: Dorment teaches a tunnel (gap, element 12) that allows powder to ingress to the internal chamber, and that the tunnel is closed when in the sealing state.

Claim 70: Dorment teaches a cap (element 9) which is exteriorly spaced to the second opening (element 7) when in the filling state (figure 2) and is sealingly seated when in the sealing state (figure 1).

Claim 71: Dorment teaches a shank section (the body of element 8) on the member that connects the cap (element 9) with the plug section (elements 8a and 8b). All other limitations in this claim are redundant as they have been addressed in the claims from which this claim depends.

Claim 72: The filling state of Dorment (figure 2) meets all limitations required in discharge state.

Finding of *prima facie* obviousness
Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the methods taught by Theobald et al. with the structural elements of Dorment, since both teach inhalation devices and methods for

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drug delivery, and produce the instant invention. The skilled artisan would have been motivated to combine the prior art teachings because Dorment teaches the inhaler as a suitable device for administering medicaments. Theobald et al. also teach inhalation delivery of medicaments; therefore, since both references teach inhalation medicament delivery, it would be obvious to combine them to produce another invention for that same purpose.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Claims 36-41 & 44-76 are rejected. Claim 36 is objected to. Claims 1-35 are withdrawn. No claims allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Lea whose telephone number is (571)270-5870. The examiner can normally be reached on Mon-Thu 7:30-5:00 ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CRL

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616